



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor : Chih-Chiang YANG	
Appln. No. : 10/828,700	
Filed : April 21, 2004	Group Art Unit: 1623
Title : COMPOSITIONS AND METHODS OF ENHANCED TRANSDERMAL DELIVERY OF STEROIDS COMPOUNDS AND PREPARATION METHODS	Examiner: G. Krishnan
Docket No. : P464.312-0001	

RESPONSE

05/09/2008 EFLORES 00000004 10020700

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180.00 OP

Mail Stop Amendment
Commissioner For Patents
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Alexandria, VA 22313-1450

SENT VIA EXPRESS MAIL

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This is in response to the Office Action mailed on February 8, 2008, in which all of the pending claims (1-6, 8-14 and 16-19) were rejected under 35 U.S.C. 103(a) as being unpatentable over Vyas et al. (International Journal of Pharmaceutics. 1998, 172, 33-70) in view of Pitha (US 4,727,064)..

In rejecting the pending claims, the Examiner contended that it would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising the cyclodextrin derivatives and the surfactants as instantly claimed since niosomes containing steroidal active agents analogous to the instant niosomes seem to be taught in the prior art. However, this is not true. In fact, **prior attempts to combine steroid-containing niosomes such as those of Vyas et al with cyclodextrin have failed.** This fact is shown in several prior publications including Ohvo and Slotte (Biochemistry 1996 35, 8018-8024), Atger *et al* (J. Clin. Invest. 1997 99(4), 773-780), and Nishijo *et al* (Chemical & Pharmaceutical Bulletin (Tokyo) 2000 48(1), 48-52), which are submitted herewith (and are listed on form PTO-1449) for review by the Examiner. These publications show that addition of cyclodextrin into a steroid-containing niosome resulted in removal of steroid compounds from the lipid bi-layer of the niosome, thereby disrupting the

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